

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of lateral wedge insole with and without subtalar strap on lateral trunk lean motion in knee osteoarthritis

Protocol summary

Summary

Purpose: To compare the effect of lateral wedge insole on lateral trunk lean motion in knee osteoarthritis to lateral wedge insole with subtalar strap. Method: 23 patients aged over 40 years with medial compartment knee osteoarthritis in one knee according to American College of Rheumatology criteria were participated in this study. They were excluded if they had bilateral knee osteoarthritis and secondary arthritis. Participants were tested in 3 conditions while walking through 3 meters walkway: without insole, lateral wedge insole and lateral wedge insole with subtalar strap. The insoles were made of High density Ethyl Vinyl Acetate with leather covered. They had 5 degree lateral wedge for involved limb and were neutral for contra lateral limb. A six camera Vicon motion analysis system was used to measure lateral trunk lean motion. 5 passive reflective markers were placed on left and right acromioclavicular joints, right and left anterior superior iliac spines and on sacrum. The immediate effect of lateral wedge insole with and without subtalar strap was compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104185520N4**

Registration date: **2011-04-29, 1390/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-29, 1390/02/09

Registrant information

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Tehran University of medical sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lateral wedge insole with and without subtalar strap on lateral trunk lean motion in knee osteoarthritis

Public title

The effect of lateral wedge insole with and without subtalar strap in patients with genoarthrosis

Purpose

Other

Inclusion/Exclusion criteria

Inclusion Criteria: 1. age between 35 to 50 years 2. at least 3 level of pain based on a ten level visual analogue scale 3. radiographic osteophyte at the joint space 4. normal or mild varus knee joint malalignment and unilateral medial tibiofemoral knee osteoarthritis 5.

grade I or II of knee osteoarthritis based on Kellgren and Lawrence knee osteoarthritis grading system. Exclusion Criteria: 1. bilateral knee osteoarthritis 2. grade III or higher of knee osteoarthritis 3. secondary knee osteoarthritis caused by trauma, knee joint surgery or other rare forms of arthritis 4. significant knee joint ligament laxity 5. previous knee joint fracture 6. therapeutic knee joint injection in previous 6 months 7. nervous system disorder that made some problems in voluntary movement 8. perception disorder 9. chronic back pain 10. lower limb discrepancy 11. experience of any orthotic treatments in knee joint or foot region 12. BMI more than 36 Kg/m² 13. hip joint or lumbar joints arthritis 14. hallux stiffness, midfoot valgus deformity, hindfoot arthropathy, foot ligament laxity, flat foot or any other problems that caused restriction for use of insole 15. knee joint valgus malalignment or knee joint recurvatum 16. problems which limited independent walking

Age

From **40 years** old to **54 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences, Rehabilitation school

Street address

Research committee, Rehabilitation School, Tehran University of Medical Sciences, Shahnazari St., Mirdamad Blvd.

City

Tehran

Postal code**Approval date**

2010-11-02, 1389/08/11

Ethics committee reference number

265

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

primary gonarthrosis, Unilateral

Primary outcomes**1****Description**

Lateral Trunk lean angle

Timepoint

before using insole and immediately after using insole with and without subtalar strap

Method of measurement

6 camera Vicon Motion analysis system

Secondary outcomes**1****Description**

walking speed

Timepoint

before using insole and immediately after using insole with and without subtalar strap

Method of measurement

Vicon motion analysis system with 6 cameras

Intervention groups**1****Description**

Lateral wedge insole and subtalar strap with Gymnastic shoes

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

University of Welfare and Rehabilitation Sciences

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr M. Moradi Lakeh

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Vice-chancellor for Research, Tehran University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty